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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/775,574

02/09/2004

Frank V. Barone JR.

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11/03/2006

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EXAMINER

LEITH, PATRICIA A

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 11/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/775,574	BARONE ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/14/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 13-16 is/are rejected.
- 7) ☒ Claim(s) 8-11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-11, 13-16 are pending in the application and were examined on their merits.

The previous rejections under 35 USC 102(b) and 35 USC 103(a) have been removed due to Applicant's amendments to the claims.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a previous Office Action.

Claim Rejections - 35 USC § 112

Claims 2-4 remain rejected and new claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues that the claims have been amended to specifically recite alcoholic extracts and therefore the amendment overcomes this rejection. However, claims 2-4 still recite the term 'extract'. New claim 14 also recites the term 'extract' and thus is rejected for the same reasoning keenly set forth in the previous Office action.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over 'Alternative Medicine Network (AMN): Women's Health' WWW site (archived to 1/28/2003) in view of Booyens (ZA 9905262 A).

To reiterate, AMN disclosed a topically applied cream for sexual fitness named 'Satisfaction' which contained L-arginine and Methyl nicotinate, *inter alia* (see pages 1 and 2 of print-out, especially page 1).

AMN did not specifically disclose wherein methyl salicylate was used in the composition.

Booyens (ZA 9905262 A) disclosed a penile massage composition which comprised methyl salicylate. As explained by Booyens, methyl salicylate improved blood supply to the penis (see entire reference, especially page 3, third full paragraph). Booyens additionally disclosed the inclusion of a moisturizing agent such as an oil (mineral or vegetable).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit

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since each is well known in the art for topical enhancement of sexual response. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Claims 1, 2, 4, 13, 14, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over 'Alternative Medicine Network (AMN): Women's Health' WWW site (archived to 1/28/2003) in view of Booyens (ZA 9905262 A) in view of Thompson (US 20020071854 A1).

The teachings of AMN and Booyens were discussed *supra*. Neither reference specifically taught the incorporation of menthol or sunflower seed oil into their compositions.

Thompson (US 20020071854 A1) taught a topically applied sexual stimulating composition comprising menthol and L-arginine (see for example [0009] and claim 1).

Again, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit

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since each is well known in the art for topical enhancement of sexual response. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

One of ordinary skill in the art would have been motivated to add an oil to a topically-applied sexual stimulatory composition in order to improve moisturization. It was clear from Booyens that oils were added to topically applied sexually stimulating compositions. It is deemed that the choice of oil would have been merely judicious selection on the part of the ordinary artisan, because whether the oil be coconut or sunflower or grapefruit seed, the oils would produce the same effect; moisturization. Accordingly, it is deemed that any type of oil which is known to be used on the skin would act as a functional equivalent to the oil as disclosed by Booyens, especially absent any unexpected results. (It is noted that claim 14 merely recites the term 'extract'. An 'extract' of grapefruit seed can encompass oil. Further, the alcohol extract would extract the oil from the grapefruit)

Claims 1-7 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over 'Alternative Medicine Network (AMN): Women's Health' WWW site

(archived to 1/28/2003) in view of Booyens (ZA 9905262 A) in view of Thompson (US 20020071854 A1) in view of Denton et al. (US 2003/0077296 A1) in view of Duckett et al. (US 6,340,480 B1) in view of Harbeck (US 2002/0817165 A1) in view of Neumayr, M (DE 04007975, English Abstract) in view of Whitely, J. (2000) and in view of Kelly (US 5,208,031).

The teachings of AMN, Booyens and Thompson were discussed supra. None of the references disclosed or suggested the incorporation of catubaa extract, muira puama extract, maca, saw palmetto, zinc or yohimbe.

Denton et al. (US 2003/0077296 A1) disclosed a topical cream for enhancing sexual response which included maca (*Lepidium meyenii*) extract, L-arginine, aloe, water and propylene glycol, *inter alia* and also specifically suggested the incorporation of catuaba extract since catuaba was a known aphrodisiac, (see claim 7 and [0004] for example).

Duckett et al. (US 6,340,480 B1) disclosed a topical ointment comprising L-arginine and saw palmetto (see claims 1 and 6 for example).

Harbeck (US 2002/0817165 A1) taught a topical composition for improving sexual arousal which comprised yohimbe in a cream base (see claims 11 and 12 for example).

Neumayr, M (DE 04007975, English Abstract) disclosed an aphrodisiac composition comprising *Muira puama* (English Abstract). It is clear that the composition is topical, in that Neumayr states 'are effective 30-60 min. after application'.

Whitely, J. (2000) reporting for the Las Vegas Review, indicated that the product 'Passion Booster' included ingredients such as nettle-root extract, muira puam extract and arginine (see p. 3 of ProQuest direct print-out).

Kelly (US 5,208,031) disclosed a sexual lubricant comprising zinc, an agent which inhibits replication of the herpes virus (see Abstract for example).

Reyes (US 6,803,060 B2) disclosed a lotion applied topically to 'boost libido' comprising vitamin E and L-arginine *inter alia* (see for example, col. 7, lines 20-27).

Again, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for topical enhancement of sexual response. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Accordingly, the instant claims, in the range of proportions where no

unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Applicant's arguments were considered as they pertain to the newly-stated rejections set forth *supra*:

Applicant argues that "The Examiner's position is that the individual ingredients of the currently-claimed compositions could have been selected from amongst the many ingredients of the cited references to successfully form a topical composition having the desired therapeutic effects....there is no motivation to combine a single ingredient from each of these reference to form the claimed compositions other than Applicant's specification" (p. 9, Arguments). Applicant additionally argues that the Examiner has relied on Applicant's specification as a 'blueprint' to deduce the obviousness rejection (*Interconnect Planning corporation v. Feil*, 227 USPQ 543).

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.).

It is obvious to combine ingredients which were known in the art which achieve the same medicinal purpose as recited in *In re Kerkhoven* as well as *In re Sussman* (see previous Office Action). the Examiner has not simply 'picked' or 'chosen' from lists of ingredients from known sexual-stimulating compositions, but cited references which teach that *each individual component* of Applicant's invention was *well-known* to have sexual-stimulating function.

"The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). The ordinary artisan would have a reasonable expectation of success in combining the Instantly claimed ingredients because each is well-known and easily found in the prior art as being sexual-stimulating agents. The mere mixture of ingredients which were already known in the art for having this purpose is considered obvious especially absent any unexpected results within the Instant specification. Further, although the Examiner has predicated the existing rejections on the mixture of individual components which were each known for causing sexual-stimulation, it is noted that the claims state 'comprising' which allows for the inclusion of an unlimited number of constituents (so long as they are not deleterious to the basic characteristics of the invention).

Claims 8-11 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655



October 24, 2006